HACCP for Medical Devices

CDRH — Center for Devices and Radiological Health

What is HACCP for Devices?

HACCP is a "Hazard Analysis and Critical Control Points" approach to medical device manufacturing and inspections. HACCP is a program where manufacturers determine their critical control points, and assure that they are in control. The program allows auditors and investigators to focus on critical control points.

HACCP programs are focused on preventing problems. Such a program allows manufacturers to zero in on critical control points that could lead to device failures or other problems. By controlling these areas, manufacturers can prevent the problems from occurring.

Why do HACCP for Devices?

By participating in the HACCP program, manufacturers will benefit by having the assurance that their critical control points are in control. Under HACCP programs, more employees develop the quality consciousness. In addition, those items audited will be the HACCP elements, thus taking the guesswork out of inspections and audits.

Who Would Implement HACCP for Devices?

Qualified device manufacturers will be eligible to participate in the HACCP program, on a phased-in basis. Entire segments of the device community, however, can be brought in at the same time.

How Would HACCP for Devices be Implemented?

Manufacturers who participate in the HACCP program would work with the Center for Devices and Radiological Health (CDRH) in implementing their program. CDRH has adopted the *general* HACCP elements used in other programs. These seven elements, which apply to all manufacturers, are already required in the Quality Systems Regulation. In addition, industry will develop the *specific* HACCP elements that apply to their particular device technologies.

7 Elements of HACCP

1. Conduct Hazard analysis and identify preventive measures
2. Identify Critical Control Points (CCP)
3. Establish critical limits
4. Monitor each CCP
5. Establish corrective action to be taken when a critical limit deviation occurs
6. Establish a record-keeping system
7. Establish verification procedures

Benefits of HACCP

- Quality monitoring of critical control points will decrease the likelihood of device problems
- Increased quality consciousness of employees
- Quality items needing correction will be readily observed
- Less time spent on inspections
- Inspections will be more efficient because they "key in" on important areas
- Increased consistency of inspections